

In re: Odidi et al.  
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Remarks/Arguments

Claims 1, 6-9, 11, 15-17, 21-32, and 34 remain in this application.

The Office Action confirms that ethyl cellulose is not a cellulose ester.

Claim Rejections- 35 U.S.C. §112, first paragraph

Claims 1, 6-9, 15-17, 21-32 and 34 are rejected under 35 USC 112, first paragraph.

Applicant respectfully traverses this rejection for the reasons outlined below.

The Office Action asserts that there is no reasonable enablement for the polymeric film being cellulose esters. The Office Action notes, for example, that the invention requires that the polymeric film be non-permeable and that the instant invention can use cellulose esters to formulate the non-permeable film; however, U.S. Patents Nos. 6,099,859 to Cheng et al. (hereinafter “Cheng”) and 6,106,864 to Dolan et al. (hereinafter “Dolan”) disclose that cellulose esters are semi-permeable rather than non-permeable.

The Office Action asserts that “Applicant argues that Dolan discloses that cellulose esters are semi-permeable rather than non-permeable. Dolan describes cellulose acetate as being both impermeable and semi-permeable”. Again, it is submitted that the Applicant did not argue that Dolan “discloses that cellulose esters are semi-permeable rather than non-permeable;” this was an actual statement made in the previous Office Action dated March 26, 2007. In fact, Applicant asserted that Dolan teaches that cellulose acetate is described as being both impermeable and semi-permeable (see column 3, lines 11-22 and 32-27). The Office Action further asserts that “Applicant argues “The cellulose esters chosen for the instant invention must be combined in the percentages claimed, and must provide the encasement coat with the features instantly claimed; be non-permeable and soluble in a pH of above about 5.0.” The Office Action further asserts that the “Applicant merely states that the correct percentages (claimed percentages) of cellulose esters would provide a non-permeable coat, which would be soluble in a pH of above about 5.0”. The Office Action further argues that “the Applicant merely states without proof that an artisan would not consider using cellulose acetate in the encasement coat since cellulose acetate would

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dissolve and form a semi-permeable membrane at pH below 5. The Examiner argues that the claims are not limited to specific cellulose esters and that the Applicant does not support the cellulose dissolution statement with data" (emphasis added). Applicant asserts that the claim recites "said encasement coat being non-permeable and soluble in a pH of above about 5.0" and if these criteria are not met, the claim is not satisfied. Therefore, since cellulose acetate is non-enteric, one skilled in the art would not consider using in the encasement coat of the claimed invention, cellulose acetate as the polymer, or more specifically, as the cellulose ester of the claimed invention since cellulose acetate would dissolve at a pH below 5.0. Therefore, one skilled in the art would know to choose cellulose esters, such as enteric cellulose esters, that would yield the specifically claimed properties of the encasement coat. Therefore, cellulose esters are enabled in the context of the claimed invention.

With respect to proof, Applicant encloses a Declaration showing that cellulose acetate dissolves at a pH below 4.0 and not at a pH above about 5.0. Therefore, cellulose acetate is clearly not a suitable polymer for the claimed invention; one skilled in the art would not choose it since it would not satisfy the criteria of the claimed invention; "said encasement coat being non-permeable and soluble in a pH of above about 5.0". The cellulose acetate does not dissolve past pH of 4.0.

Applicant, therefore, has provided evidence to affirm the statement that cellulose acetate would possess dissolution properties unsuitable for the claimed invention. Cellulose acetate would dissolve at a pH of 1 to 2. Therefore, a coat of cellulose acetate will dissolve at a pH in the gastric range and thereby release its contents without lag time. For these reasons, cellulose acetate would not have been expected to meet the extended release properties of the claimed invention. The extended release formulation of the claimed invention will remain intact until experiencing a pH of above about 5, and will only then dissolve, therefore providing an extended release.

Claim Rejections- 35 U.S.C. §103(a)

1, 6-9, 11, 15-17, and 21-34 (claim 33 was cancelled in the previous Office Action)

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remain rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,106,864 to Dolan et al. (hereinafter "Dolan") and U.S. Patent No. 5,800,422 to Dong et al. (hereinafter "Dong") and U.S. Patent No. 6,099,859 to Cheng (hereinafter "Cheng").

The Office Action asserts that Dolan teaches oral dosage forms of actives and teaches that a matrix comprising the active can be coated with an impermeable coating (see column 2, lines 53-57; see column 3, lines 1-7). It is submitted, however, that Dolan actually teaches that the impermeable coating is non-enteric (as noted in the description at Column 3, lines 15-18 with respect to the examples provided) and must have an aperture (see column 3, lines 1-7 and lines 11-21).

The Office Action also asserts that Dolan teaches that ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives as well as with semi-permeable coatings such as cellulose esters (ethyl cellulose, cellulose acetate) and acrylic polymers (see column 3, lines 7-38). (Please note that ethyl cellulose is not a cellulose ester; as acknowledged by the Office Action). Dolan's coat is either impermeable with an aperture, as noted in (c) at column 2, lines 42-44 and column 3, lines 11-21, or the coat can have low aqueous solubility (e.g. water soluble at pH >5), as noted in (d) at column 2, lines 46-47, and column 3, lines 22-30. Dolan teaches the use of non-enteric cellulose esters (soluble in the acidic pH range), such as cellulose acetate, in conjunction with an impermeable coat, as noted in (c) at column 3, lines 11-21, and with a semi-permeable coat, as noted in (e) at column 3, lines 32-37. Dolan does not teach or suggest an encasement coat, as a whole, being both non-permeable and soluble in a pH of above about 5.0, as claimed in the present invention. PEG is used in the coat of the claimed invention to achieve the non-permeability (e.g. not permeable; no drug goes through) of the coat that is soluble at a pH of above about 5.0. Therefore, the Office Action's assertion that "Dolan teaches that the active ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) which are impermeable and soluble at pH greater than 5 (Dolan column 3, lines 7-38)" is incorrect. Moreover, if the coating of Dolan is non-permeable, it would include an aperture and be non-enteric, as taught at Column 3, lines 15-18. Dolan does not teach or suggest a coat being both

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non-permeable and soluble in a pH of above about 5.0.

The Office Action asserts that Dong teaches the use of PEG in a coating and that it would have been obvious to include PEG in the coating of Dolan. Applicant respectfully disagrees. The specific combination of the claimed invention (e.g. polymer and PEG) yields a coating that is both non-permeable and soluble in a pH of above about 5.0. One skilled in the art would not consider adding PEG to the coating of Dolan to achieve an impermeable coat (e.g. non-permeable coat) since an impermeable coat of Dolan is associated with non-enteric coats (dissolve at pH below 5.0; see Column 3, lines 15-18 of Dolan).

The Office Action also asserts that Cheng teaches that PEG is a flux-enhancing agent, which allows the drug to be released through the pores of the coat. The Office Action further asserts that it would have been obvious to modify the invention of Dolan to include the PEG to enhance the release of the drug through the pores. As noted above, the PEG is used in the claimed invention to aid in making the coating non-permeable. Therefore, one skilled in the art would not consider adding PEG to the coating of Dolan to achieve an impermeable coat since Cheng clearly teaches that PEG makes the coating permeable.

For these reasons, it is respectfully submitted that Claims 1, 6-9, 11, 15-17, 21 to 32, and 34 are patentable over Dolan, Dong and Cheng. Dong and Cheng do not overcome the above-noted deficiencies of Dolan.

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**Conclusion**

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of all of the pending claims 1, 6-9, 11, 15-17, 21-32, and 34, and the issuance of a Notice of Allowability are respectfully solicited.

In the event that this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Sim & McBurney's Account No. 192253, referencing docket number **9577-25 LAB**.

Respectfully submitted,

**SIM & McBURNEY**

By \_\_\_\_\_

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